



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0655]

Animal Generic Drug User Fee Act; Stakeholder Consultation Meetings on the Animal Generic Drug User Fee Act Reauthorization; Request for Notification of Stakeholder Intention to Participate

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for notification of participation.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing this notice to request that public stakeholders notify FDA of their intent to participate in periodic consultation meetings on reauthorization of the Animal Generic Drug User Fee Act (AGDUFA). The statutory authority for AGDUFA expires September 30, 2018. The Federal Food, Drug, and Cosmetic Act (the FD&C Act) requires that FDA consult with a range of stakeholders--including patient and consumer advocacy groups, veterinary professionals, and scientific and academic experts--in developing recommendations for the next AGDUFA program, and hold discussions with these stakeholders at least once every 4 months during FDA's negotiations with the regulated industry. The purpose of this request for notification is to ensure continuity and progress in these regular discussions by establishing consistent stakeholder representation.

DATES: Submit notification of intention to participate in continued periodic stakeholder consultation meetings regarding AGDUFA reauthorization by May 16, 2016. These stakeholder meetings are expected to commence in June/July 2016 and will continue at least once every 4 months during reauthorization negotiations with the regulated industry. See the

SUPPLEMENTARY INFORMATION section for further information regarding notification of intention to participate.

ADDRESSES: The stakeholder meetings will be held at the Food and Drug Administration, Center for Veterinary Medicine, 7519 Standish Pl., Rockville, MD 20855.

FOR FURTHER INFORMATION CONTACT: Cassie Ravo, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-6866, FAX: 240-276-9744, Cassie.Ravo@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

In 2013 Congress passed the Animal Generic Drug User Fee Amendments of 2013 (Pub. L. 113-14; AGDUFA II). The authority for AGDUFA II expires September 30, 2018. Without new legislation to reauthorize the program, FDA will no longer be able to collect user fees for future fiscal years to fund the generic new animal drug review process. Section 742(d)(1) of the FD&C Act (21 U.S.C. 379j-22(d)(1)) requires that FDA consult with a range of stakeholders in developing recommendations for consideration for the next AGDUFA program, including representatives from patient and consumer advocacy groups, veterinary professionals, and scientific and academic experts. To initiate this process of consultation, elsewhere in this issue of the Federal Register, we are announcing a public meeting to be held on May 16, 2016, where stakeholders and other members of the public will be given an opportunity to present their views on the reauthorization. The meeting and written comments submitted to the docket will provide critical input as the Agency prepares for reauthorization discussions. Section 742(d)(3) of the FD&C Act further requires that FDA continue meeting with these stakeholders at least once

every 4 months during negotiations with the regulated industry to continue discussions of their views on the reauthorization, including suggested changes to the AGDUFA program.

FDA is issuing this Federal Register notice to request that stakeholders--including veterinary, patient and consumer groups, as well as scientific and academic experts--notify FDA of their intent to participate in the periodic consultation meetings on AGDUFA reauthorization. FDA believes that consistent stakeholder representation at these meetings will be important to ensure progress in these discussions. If you wish to participate in this part of the reauthorization process, please designate one or more representatives from your organization who will commit to attending these meetings and preparing for the discussions. Stakeholders who identify themselves through this notice will be included in all future stakeholder discussion while FDA negotiates with the regulated industry. If a stakeholder decides to participate in these meetings at a later time, they may still participate in remaining meetings by notifying FDA (see ADDRESSES). These stakeholder discussions will satisfy the requirement in section 742(d)(3) of the FD&C Act.

II. Notification of Intent to Participate in Periodic Stakeholder Consultation Meetings

If you intend to participate in continued periodic stakeholder consultation meetings regarding AGDUFA reauthorization, please submit notification by email to: cvmagdufa@fda.hhs.gov by May 16, 2016. Your email should contain complete contact information for each attendee, including name, title, affiliation, address, email address, telephone number, and notice of any special accommodations required due to a disability. Stakeholders will receive confirmation and additional information about the first meeting after FDA receives this notification.

Dated: April 12, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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